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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,040	03/01/2002	Joseph C. Cauthen	08442.0002-04	8078

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EXAMINER	
CHATTOPADHYAY, URMI	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/085,040	CAUTHEN, JOSEPH C.	
	Examiner	Art Unit	
	Urmi Chattopadhyay	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *45-62 and 64-93* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45-62 and 67-93* is/are rejected.

7)☒ Claim(s) *64-66* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/20/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed 3/24/04 has been entered. Changes to Figures 9 and 11B-11D have been approved by the examiner. Claim 63 has been canceled and new claims 89-93 have been added. The claims being considered for further examination on the merits are 45-62 and 64-93.

2. The indicated allowability of claims 46-48 is withdrawn in view of the reference(s) to Gilson (USPN 5,904,703), which was cited in applicant's most recent filed IDS (5/20/04). Rejections based on the newly cited reference(s) follow.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 5/20/04 was filed after the mailing date of the non-final office action on 9/25/03. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 45-48, 58, 60, 67-69, 86 and 87 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject

matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The following claim limitations from the new claims are considered new matter:

a. Claim 45 (amended): "*at least one* lateral extension" on line 3. In at least [038] of the specification, applicant discloses the device as having a *pair* of lateral extensions, specifically left lateral extension (20) and right lateral extension (22). Two lateral extensions are clearly shown in the figures as well. The claimed limitation of "at least one lateral extension" is broader in scope than what is disclosed by the applicant as the invention because it includes an embodiment where the device includes only one lateral extension. This embodiment is neither disclosed nor enabled by the specification. The written description requirement, therefore, has not been met.

b. Claim 58: "polyethylene". Applicant argues that the specification's recitation of the use of biocompatible materials such as medical grade fabrics, fibers of polymer, or biodegradable polymeric sheets, in addition to the art recognized use of polyethylene as an implantable biocompatible material, and the further citation of Pease (USPN 2,671,444) to teach a polyethylene fabric patch, are sufficient in meeting the written description requirement. The examiner disagrees. The specification does not specifically disclose polyethylene as the biocompatible material and it is not inherent that the biocompatible material would be polyethylene. Therefore, the written description requirement is not met.

c. Claim 60: "polytetrafluoroethylene". Applicant argues that ePTFE and PTFE are different in their physical properties, but are the same chemically. The examiner agrees.

However, it is because they are different in their physical properties that the disclosure of the device comprising ePTFE does not necessarily include disclosure of PTFE for the device material.

d. Claims 67-69: time of "aperture dimension" measurement. This was not addressed by the applicant in the amendment. The rejection is maintained.

e. Claims 86 and 87 (both amended): "at least as large" as said defect/aperture. This limitation is broader in scope than what is disclosed in the specification because it includes an embodiment that has a second dimension that is exactly as large as the defect/aperture, which is not disclosed. It appears from the last paragraph on page 13 of the amendment that applicant had intended to amend claims 86 and 87 in the same manner as claim 49, specifically by changing "at least as large as" to --larger than--. This amendment, however, had not been made to the claims and the rejections are therefore maintained.

Priority

6. Independent claims 86 and 87 were originally presented in a preliminary amendment filed on 3/17/03, which is after the filing date of the application of 3/1/02. Original claims 86 and 87 both contain a limitation that does not meet the written description requirement, and therefore constitutes new matter. Specifically, the limitation of the second dimension being "at least as large as" the defect/aperture is new matter. The claims were amended but still include the new matter limitation. When a new matter limitation is introduced into a claim that is otherwise fully supported by the original specification, the combination of limitations in this new claim defines an invention that is not fully supported by the original specification. Therefore,

claims 86 and 87 as a whole do not receive benefit of the earlier filing dates of the parent and provisional applications. The effective filing date of claims 86 and 87 is the filing date of the application, 3/1/02.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 45-48 and 89-91 are rejected under 35 U.S.C. 102(e) as being anticipated by Gilson (USPN 5,904,703, as cited in applicant's IDS).

Gilson discloses an occluder device with all the elements of claims 45 and 89. See Figure 3 for a centralized vertical extension (11) connected at one end to a lateral extension (4 or 5). See Figure 9 for the centralized vertical extension (11) comprising a recess (lumen through vertical extension) between an upper section (end portion that is gripped by a tool) and a lower section (end portion opposite the tool gripped end portion). Because the structural limitations of the claim are met, the occluder of Gilson is inherently capable of repairing an aperture in an intervertebral disc by providing as an annulus stent. The lateral extension (4 or 5) is capable of being placed in the subannular space. The centralized vertical extension (11) is configured to form a non-sealing fit with the aperture because the extension is surrounded by neck portion (6)

and does not even come into contact with the aperture. Additionally, the occluder would capable of forming a non-sealing fit with the aperture if it was used for an aperture larger than the neck portion (6), and the occluder would capable of forming a compatible fit with the aperture if it was used for an aperture comparable in size to the neck portion (6).

Claims 46 and 89, see Figure 9 for the upper section comprising a slot, which forms an orifice (36) through the upper section.

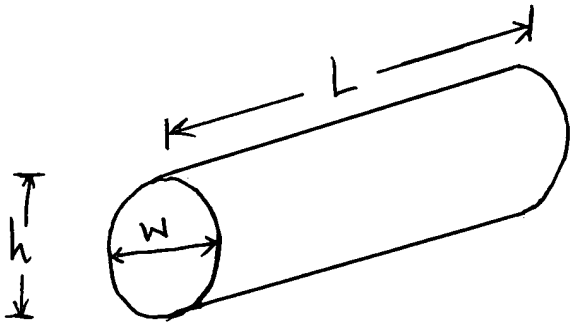
Claims 47 and 90, see Figure 9 for the slot (36) traversing the longitudinal axis of the upper section.

Claims 48 and 91, see Figure 9 for the slot (36) being size and shaped to accommodate sutures, bands, or staples.

9. Claims 49-62, 67-85, 88, 92 and 93 are rejected under 35 U.S.C. 102(e) as being anticipated by Bao et al. (USPN 6,224,630 as cited in applicant's IDS).

Bao et al. discloses an implantable device for therapeutically or prophylactically treating the annulus of a patient's intervertebral disc, the annulus having an aperture having an aperture dimension along a selected axis, the device having delivery and implanted configurations with all the elements of claims 49 and 88. See columns 7-8, lines 61-9 for the device comprising a body in the form of a cylindrical plug (width and height are the same). The plug has an interior end that is adapted to expand disproportionately more than the barrel such that the interior portion forms an internal lock upon insertion. This means that in a delivery configuration, the device has a width (first dimension) no larger than the aperture it is being implanted into so that it is capable of passing substantially through the aperture. Also, in an implanted configuration, the device has

a height (second dimension) at an interior end that is larger than the aperture, thereby spanning the aperture subannularly substantially along the selected axis and restricting the migration of intradiscal material through the aperture. The fit of the device with respect to the aperture will depend on their respect sizes. Because all of the structural limitations of the product claim are met, the device of Bao et al. is capable of meeting the claimed functional requirements as well. The enlarged interior end of the device of Bao et al. is capable of spanning the aperture subannularly with substantially no trauma to the aperture if the aperture is larger than the maximum enlarged size of the barrel portion of the device. Even though the Bao et al. discloses the device as a plug, it is structurally capable of being used in other fashions. Applicant is reminded that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). There is no *structural* difference between the claimed invention and the device of Bao et al.



With respect to claim 50, the second dimension (height) lies along a different axis than the first dimension (width).

With respect to claims 51-53, the cylindrical plug in its unexpanded delivery configuration is certainly *capable* of subannular reorientation comprising rotation (about its longitudinal axis) or deformation.

Claim 54, see column 8, lines 1-2 for second dimension (height at interior end) resulting from expansion of the device from the delivery configuration. Also see column 4, lines 50-54.

Claims 55, 56 and 67-69 do not further structurally limit the device. How and when the aperture dimension is measured does not affect the structure of the device.

Claim 57, see column 5, line 34 for synthetic biocompatible material.

Claim 58, see column 5, line 43 for polyethylene.

Claim 59, see column 6, line 23 for bioresorbable material.

Claim 60, see column 5, line 57 for PTFE.

Claim 61, see column 4, lines 35-40 for material facilitating regeneration of disc tissue.

Claim 62, see column 4, lines 50-53. Because the device material will expand upon release of a constraining means, it is inherent that the material is of a flexible, resilient material.

Claims 70 and 71, see column 5, lines 31-58 and column 7, line 57 for polymeric sheet.

Claims 72 and 73, see column 9, lines 61-65 for the device being formed at least in part from allograft or autograft.

Claim 74, see column 4, lines 5-9 for the device being formed at least in part from xenograft.

Claim 75, see column 14, line 21 for porous mesh.

Claim 76, see column 5, lines 36-39 for fibrous material.

Claim 77, see column 4, lines 22-49 for biocompatible fabric.

Claim 78, see column 14, lines 19-27 for attachment element.

Claims 79 and 80 do not further structurally limit the device. The anatomical features to which the attachment element is fixating the device do not affect the structure of the device.

Claims 81-85, see column 14, lines 17-24 for attachment means.

Claim 92, see column 6, lines 40-43 for polymer fibers.

Claim 93, see column 9, lines 23-40 for tissue growth factor.

10. Claims 86 and 87 are rejected under 35 U.S.C. 102(b) as being anticipated by Bao et al.

Bao et al. discloses an implantable device for treating a defect/aperture in an intervertebral disc annulus with all the elements of claims 86 and 87. See rejection to claims 49 and 88, supra.

11. Claims 86 and 87 are rejected under 35 U.S.C. 102(e) as being anticipated by Lambrecht (USPN 6,425,919 as cited in last office action).

The effective filing date of claims 86 and 87 is the filing date of the application, 3/1/02 (see Priority paragraph, supra). The embodiment used in the rejection below has an effective filing date of the date of filing of the Lambrecht patent, 6/30/00.

Lambrecht discloses a disc herniation constraining device with all the elements of claims 86 and 87. See Figures 29B-C for a device (12) for treating a spinal disc annulus having a defect/aperture (16). The device comprises a delivery/collapsed configuration (Figures 29A-

29B) wherein the device has a width (first dimension) no larger than the aperture it is being implanted into (the width is the width of the delivery tool). Therefore, it is structurally configured to be capable of being passed into and through the defect/aperture (16) in a first delivery/collapsed configuration. Also, the device has an implanted/expanded configuration (Figures 29C-29D) wherein the device has a height (second dimension) that is larger than the aperture. See column 17, lines 1-4 for the device (12) spanning the aperture (16) and extending along the interior aspect (36) of the annulus (10) until it contacts healthy tissues on all sides of the aperture (16), thereby restricting the migration of intradiscal material therethrough. There is substantially no trauma to the aperture.

Allowable Subject Matter

12. Claims 64-66 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

13. Applicant's arguments with respect to claims 45-62 and 64-93 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

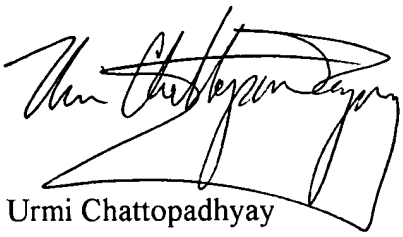
14. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 5/20/04 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

15. Applicant's amendment also necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

16. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 872-9306. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.



Urmi Chattopadhyay

Art Unit 3738

David J. Isabella
Primary Examiner